REMARKS

Claims 55-81 were pending in the application. Claims 1-54 have been cancelled, without prejudice, be previous amendment. In particular, claims 1-6, 19-20, and 51-54 have been cancelled and claims 7-18 and 21-50 have been cancelled for being directed to a non-elected invention. Claims 55, 57-63, 65, and 68-78, have been withdrawn as being directed to a non-elected invention. Claims 56 and 64 have been amended. New claims 82-91 have been previously presented and have been amended herein to recite the "penile tissue" of a subject. After the amendments presented herein have been entered, claims 56, 64, 66-67, and 79-91 will be pending.

Support for amendments to the claims may be found throughout the specification and originally filed claims. In particular, support for amendments to claims 56, 64, 82, 83, 89, and 91 may be found, for example, at page 2, lines 10-11 and at page 6, lines 16-20 of the specification. Support for the term "phosphodiesterase type 5 inhibitor" as set forth in claims 89 and 90 may be found at page 2, lines 6-10 of the specification.

Amendment and cancellation of the claims herein should in no way be construed as an acquiescence to any of the rejections/objections set forth in the instant Office Action, or in any previous Office Action, and were done solely to expedite prosecution of the above-identified application. Applicants reserve the option to prosecute the same or similar claims as those originally filed in the instant application or in this or one or more or subsequent applications. *No new matter has been added.*

Election/Restriction

The Examiner has withdrawn claims 55, 57, 58-63, 65, and 68-78 as being directed to a non-elected invention. Applicants respectfully traverse the requirements for restriction and election, and submit that the requirements are improper. First, Applicants assert that the subject matter of the restricted claims represent different embodiments of a single inventive concept for which a single patent should issue. The pending claims represent an intricate web of knowledge, continuity of effort, and consequences of a single invention, which merit examination of all of these claims in a single application. More particularly, a single, searchable, unifying aspect, *i.e.*,

a device for promoting transdermal absorption of one or more therapeutic agent(s), links all of the claims.

Second, Applicants submit that a sufficient search and examination with respect to the subject matter of all claims can be made without serious burden. As the M.P.E.P. states:

> [i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. M.P.E.P. § 803 (7th ed., Rel. 78A, March 1999).

That is, even if the above-enumerated groups of claims are drawn to distinct inventions, the Examiner must still examine the entire application on the merits because doing so will not result in a serious burden.

Applicants submit that the search and examination of all the claims will have substantial overlap, and no serious burden will result from searching and examining all claims in the same application.

Furthermore, Applicants elected Group I directed to a device for transdermal administration of topical therapeutic agents. The Examiner has determined that independent claim 64, which is directed to a device for promoting transdermal absorption, is properly grouped within the elected invention. Thus, at a minimum, claims 68-78, which are dependent upon claim 64, and further specify the claimed device for promoting transdermal absorption, should be grouped within the elected group.

Accordingly, Applicants respectfully request reconsideration of the restricted claims.

Drawings

The Examiner has objected to the drawings because reference number "27" was not shown in Figure 9 and reference numerals "60" and "20c" were not shown in Figure 10. Lastly, Figure 10 does not have a transversal cut to show what is shown in Figure 11. Applicants respectfully submit that Figures 9-11 have been amended to render the foregoing objections moot. Accordingly, Applicants respectfully request withdrawal of the objection.

Specification

The Examiner objects to the specification as failing to provide proper antecedent basis for the claimed subject matter. In particular, the Examiner states "[c]orrection of the following is required: the device comprising a battery as set forth in claim 80 for the elected species."

Applicants submit that support for claim 80 may be found in original claim 20 and in the specification at page 8, lines 19-22. Thus, Applicants respectfully request withdrawal of the foregoing objection.

Rejection of the Claims Under 35 U.S.C. §102(e)

The Examiner has rejected claims 56, 64, and 79-81 under 35 U.S.C. §102(e) as being anticipated by Ogden (U.S. Patent No. 5,656,016). According to the Examiner, Ogden discloses a therapeutic drug delivery device comprising an applicator 12, an ultrasound transducer, and a detector for monitoring feedback signals from the transducer.

Applicants respectfully traverse the foregoing rejection for the following reasons. For a prior art reference to anticipate in terms of 35 U.S.C. § 102 a claimed invention, the prior art must teach ***each and every element*** of the claimed invention. Lewmar Marine v. Barient, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

Applicants' claims are drawn to a device for promoting transdermal absorption of one or more therapeutic agent to a penile tissue surface of a subject, which encompass the use of an applicator for applying an effective amount of one or more agent(s) and an ultrasound means operatively coupled to the applicator, for providing ultrasound energy to the penile tissue surface that operates at one or more predetermined frequency to promote transdermal absorption of the one or more agent(s) through the penile tissue of the subject. Ogden *et al.* fails to teach or suggest such a device which penetrates a ***penile tissue surface***, as claimed.

Ogden broadly describes that the invention pertains to a sonophoretic drug delivery system using ultrasound for transdermal penetration of an agent or drugs including pharmaceuticals, proteins, vitamins, inorganic and organic compounds as well as other substances, through the skin and into the circulatory system. However, Ogden *et al.* ***fails to***

teach or suggest a device for transdermal absorption of a therapeutic agent to a ***penile tissue*** of a subject, as claimed by Applicants.

Accordingly, as Ogden *et al.* fails to teach ***each and every element*** of the claims, Applicants respectfully request that this section 102(e) rejection be reconsidered and withdrawn.

Rejection of the Claims Under 35 U.S.C. §102(e)

The Examiner has rejected claims 56, 64, 66, 67, 80, and 81 under 35 U.S.C. §102(e) as being anticipated by Bock (U.S. Patent No. 5,618,275). According to the Examiner, Bock discloses a ultrasonic device having an applicator 1, 2, 3, and an ultrasound transducer.

Applicants respectfully traverse the foregoing rejection for the following reasons. For a prior art reference to anticipate in terms of 35 U.S.C. § 102 a claimed invention, the prior art must teach ***each and every element*** of the claimed invention. Lewmar Marine v. Barient, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

Applicants' claims are drawn to a device for promoting transdermal absorption of one or more therapeutic agent to a penile tissue surface of a subject, which encompass the use of an applicator for applying an effective amount of one or more agent(s) and an ultrasound means operatively coupled to the applicator, for providing ultrasound energy to the penile tissue surface that operates at one or more predetermined frequency to promote transdermal absorption of the one or more agent(s) through the penile tissue of the subject. Bock fails to teach or suggest such a device which penetrates a ***penile tissue surface***, as claimed.

Bock broadly describes ***low frequency*** ultrasonic pressure waves are applied to the skin of sufficiently high intensity to cause cavitation in the skin which facilitates penetration of a therapeutic agent such as medicine or a cosmetic such as a moisturizer. In particular, Bock shows an ultrasonic device which generates ultrasonic waves in the frequency range of 15,000 to 25,000 Hertz (col. 4, ls. 27-29). Bock fails to teach or suggest the claimed device which includes a high frequency range of between 100 kHz and 4 MHz. In fact, Bock teaches away from using the frequency range encompassed by the claimed invention. Thus, Bock *et al.* ***fails to teach or suggest*** a device for transdermal absorption of a therapeutic agent to a ***penile tissue*** of a subject, as claimed by Applicants.

Accordingly, as Bock *et al.* fails to teach ***each and every element*** of the claims, Applicants respectfully request that this section 102(e) rejection be reconsidered and withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. CMZ-117RCE from which the undersigned is authorized to draw.

Dated: November 7, 2003

Respectfully submitted,

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ANNOTATED SHEET SHOWING CHANGES

"20" Deleted → 27 [20]
"27" Added

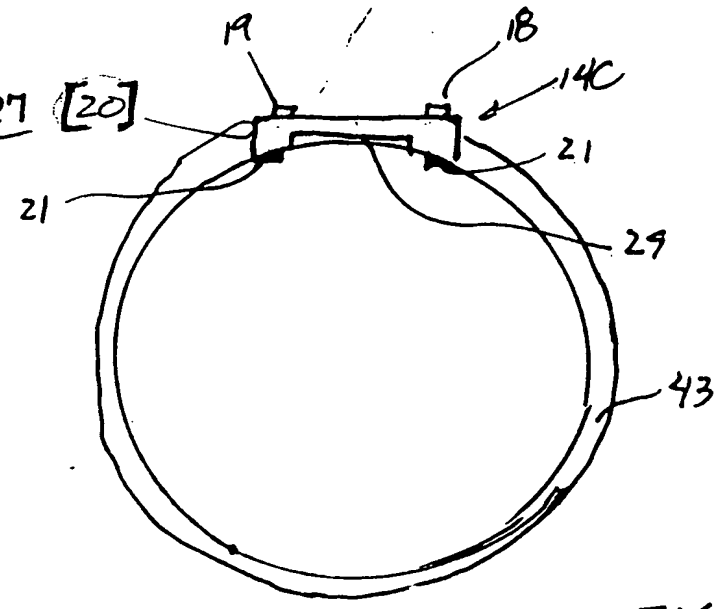

FIG. 9

"60" Added

"20C" Added → 20C

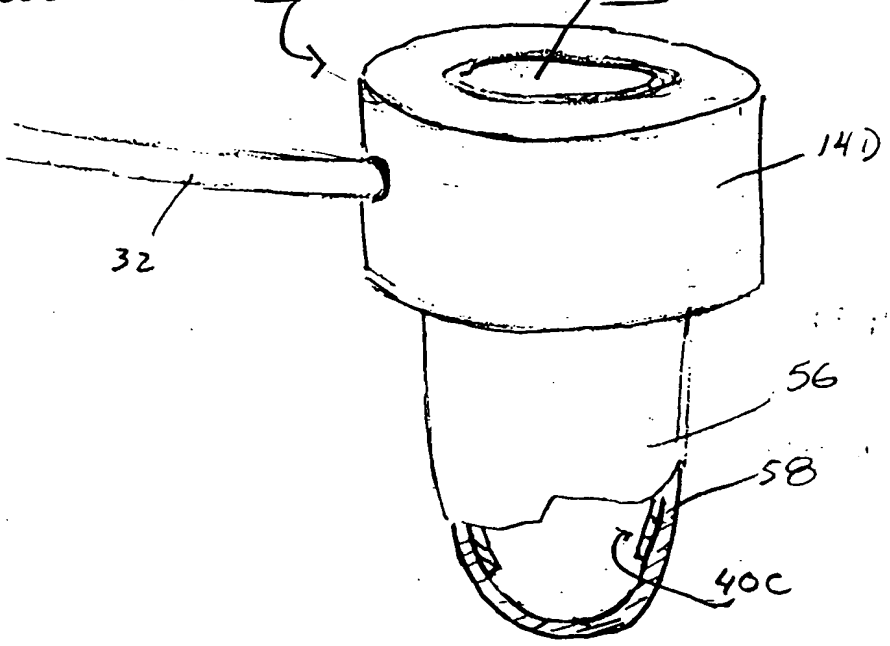

FIG. 10

ANNOTATED SHEET SHOWING CHANGES

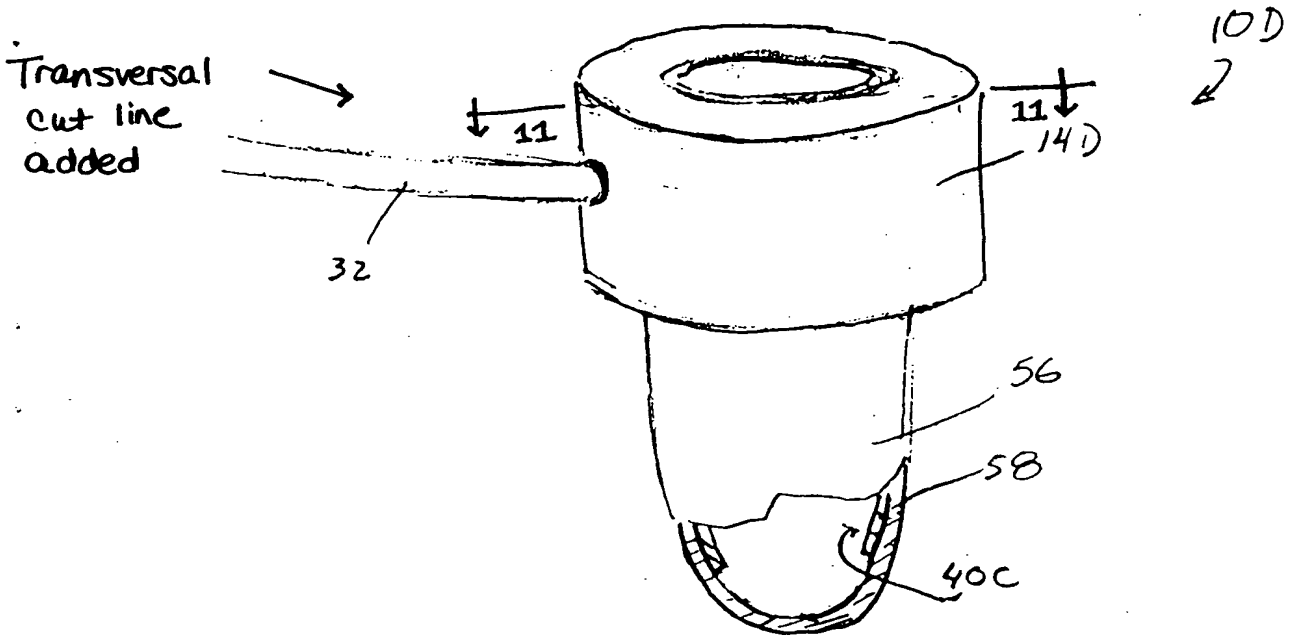

FIG. 10